Medical Devices

Reclaim™ DBS™ Therapy for OCD - H050003

FDA approved this device under the Humanitarian Device Exemption (HDE) program[1]. See the links below to the Summary of Safety and Probable Benefit (SSPB) and other sites for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Reclaim™ Deep Brain Stimulation for Obsessive Compulsive Disorder (OCD) Therapy
Manufacturer: Medtronic Neuromodulation
Address: 7000 Central Avenue NE, Mail Stop RCW 235, Minneapolis, MN 55432-3576
Approval Date: February 19, 2009

Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf5/H050003a.pdf[2]

What is it? A totally implanted brain stimulator intended to suppress symptoms associated with Obsessive Compulsive Disorder (OCD) that are not adequately controlled with medications and/or other therapies.

How does it work? An implanted pulse generator (IPG) is connected with a lead extension, to a lead with four electrodes. The electrodes contact the patient at a specific anatomical structure within the brain. The IPG is implanted under the skin of either the abdomen or under the clavicle, and sends programmable electrical stimulation pulses to a selected combination of output electrodes within the brain. Two of these device systems may be implanted to stimulate both sides of the brain in order to relieve symptoms or one device with two lead outputs.

When is it used? This device is indicated to be used in conjunction with medications for the treatment of chronic, treatment resistant adult OCD patients to aid in the management of the symptoms.

What will it accomplish? The Reclaim™ system may improve some of the symptoms associated with OCD; however, individual results vary and the specific benefit for an individual patient cannot be predicted.

When should it not be used? In patients who will be exposed to diathermy, in patients who will be exposed to MRI using a full body radio-frequency coil or a head transmit coil that extends over the chest, in patients for whom test stimulation is unsuccessful, and in patients who are unable to properly operate the brain stimulator.

Additional information:

- SSPB and Labeling[3]

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